

April 8, 1999

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William K. Hubbard  
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Federal Register Request for Information: Performance Standard for *Vibrio vulnificus*  
Docket number 98P-0504-Volume 64, Number 13, Page 3300-3301

Dear Mr. Hubbard,

I have reviewed your request for comments, with supporting data where appropriate, on your eight questions that relate to issues raised by the CSPI petition.

1. The AmeriPure process is said to add .08 cents per oyster in cost, this is .96 cents/dozen. This would make our product unacceptable to the market place.
2. My company knows of no technologies available that could reduce the number of *V. vulnificus*. Following rules developed with FDA, ISCC, and the shellfish farmers has offered viable options to so called technology.
3. N/A see #2.
4. Performance standards that utilize "non-detectable" are close to impossible to meet. As science improves we will continue to push these limits downwards. What science does FDA utilize to determine significant levels of pathogens?
5. I don't believe there is good science to establish a performance standard.

I am an oyster farmer, not well versed in the political system. I am unaware as to how a private non-profit group has the capacity to effect change of this magnitude. I would hope that FDA would have the abilities and resources to do the science on this issue before creating policy based upon a petition. To the best of my understanding of how ISSC, FDA, the States and the growers work on issues of public health concerning shellfish, it would seem obvious that we all should be working through the ISSC which was created to handle exactly this type of issue.

Thank you for taking the time to review my concerns.

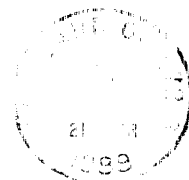
Sincerely,

*James L. Kemmer*  
*Long Island Oyster Co.*

98P-0504

C228

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Box 1054  
Long Beach Wash  
98631



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